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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,575	04/13/2001	Arthur Lander	82351.0003	9101

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/807,575	LANDER ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08/03/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *7-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2006 has been entered.

2. Claims 1-18 are pending.

Claims 1 and 3-5, have been amended.

Claims 17 and 18 have been added.

Claims 7-16, drawn to non-elected inventions are withdrawn from examination.

Claims 1-6, 17 and 18 are examined on the merits to the extent the binding molecule bind to glypican-1.

Withdrawn Objection

Claim Objections

3. The objection of claims 1, 3 and 4 is withdrawn in light of the amendment to the claims.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1 and 5 recite "and *an* information". This language is indefinite. Information is knowledge communicated or received and not regarded as a single entity as noted in the claims. Applicants may obviate the rejection by amending the claim to recite "and information".

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). Applicants' preamble reads on intended use, as well as kits, which read on intended use and do not

have patentable weight. Birembaut discloses the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section.

8. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants assert claims have been amended by adding further elements to provide meaning to the claims and tying the preamble to the claim elements, see Remarks submitted August 3, 2006, 3rd paragraph. Applicants aver the elements of the newly amended claims "...are neither inherently nor literally present in the cited references", see bridging paragraph of pages 6 and 7 of the Remarks. These points of view have been carefully reviewed and considered, but found unpersuasive.

As stated in the Action mailed March 23, 2006 Applicants' preamble reads on intended use, which does not have patentable weight. The amendment of the claims to include kit language also does not preclude the instant rejection, because this reads on intended use as well and does not have patentable weight. The anti-glypican antibody disclosed by Karthikeyan would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes

human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Karthikeyan discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 3213, "Preparation of antibodies..." section, first sentence. Attached to the said antibody was a peroxidase-conjugated goat anti-rabbit IgG, thereby aiding in imaging, see page 3216, column 1, paragraph before "In situ..." section and Figure 5. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid and would impart information associated with the expression of glypican-1.

9. The rejection of claims 1-6 under 35 U.S.C. 102(b) as being anticipated by Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Karthikeyan reference. These points of view have been carefully considered, but found unpersuasive.

As stated in the Action mailed March 23, 2006 Applicants' preamble reads on intended use, which does not have patentable weight. The amendment of the claims to include kit language also does not preclude the instant rejection, because this reads on intended use as well and does not have patentable weight. The anti-glypican antibody disclosed by Ivins would inherently detect one of human breast cancer and pancreatic

cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Ivins discloses 343-1, an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 321, "Antipeptides..." section, last sentence. Attached to the said antibody was a Cy3-conjugated goat anti-rabbit antibody for immunofluorescence, thereby aiding in imaging, see page 325, paragraph before "Proteoglycan..." section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid and would impart information associated with the expression of glypican-1.

10. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants assert, "Liang et al. teach compositions and methods for detection of glypican...in various non-cancerous rat neuronal tissues" and this reference fails to teach compositions and use of the glypican antibodies as presently claimed, see Remarks, page 7, last paragraph. These points of view have been carefully reviewed and considered, but found unpersuasive.

As stated in the Action mailed March 23, 2006 Applicants' preamble reads on intended use, which does not have patentable weight. The amendment of the claims to

include kit language also does not preclude the instant rejection, because this reads on intended use as well and does not have patentable weight. The anti-glypican antibody disclosed by Liang would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Liang discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 852, "Antibodies..." section, first sentence. Attached to the said antibody was a peroxidase-conjugated goat anti-rabbit IgG, thereby aiding in imaging, see page 852, "Electrophoresis..." section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid and would impart information associated with the expression of glypican-1.

11. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Liang reference. These points of view have been carefully considered, but found unpersuasive.

As stated in the Action mailed March 23, 2006 Applicants' preamble reads on intended use, which does not have patentable weight. The amendment of the claims to

include kit language also does not preclude the instant rejection, because this reads on intended use as well and does not have patentable weight. The anti-glypican antibody disclosed by Litwack would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Litwack discloses 343-1, an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 77, "Expression..." section and page 85, "Anti-Peptide Antibodies" section. Attached to the said antibody was a Cy3-conjugated goat anti-rabbit antibody, thereby aiding in imaging, see page 85, "Immunohistochemistry" section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid and would impart information associated with the expression of glypican-1.

12. The rejection of claims 1-6 under 35 U.S.C. 102(a) as being anticipated by Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998) is maintained.

Applicants' arguments are essentially the same as those provided against the Liang reference. These points of view have been carefully considered, but found unpersuasive.

As stated in the Action mailed March 23, 2006 Applicants' preamble reads on intended use, which does not have patentable weight. The amendment of the claims to include kit language also does not preclude the instant rejection, because this reads on intended use as well and does not have patentable weight. The anti-glypican antibody disclosed by Liu would inherently detect one of human breast cancer and pancreatic cancer because Kleeff notes an anti-rat glypican-1 antibody recognizes human glypican-1, see Kleef, page 1663, column 2, Immunohistochemistry section, first sentence. Consequently, Liu discloses an anti-glypican antibody, which corresponds to the extracellular region of glypican-1 and would consequently cleave an extracellular region of glypican-1 and suppress expression of an extracellular region of glypican-1, see page 22829, Figure 5 and the first paragraph of the "Characterization..." section. Attached to the said antibody was a biotinylated goat anti-rabbit IgG, thereby aiding in imaging, see page 22827, last two sentences of the "Western Blotting" section. It is reasonable to conclude that the disclosed antibody is a diagnostic agent capable of detecting human glypican-1 and in a body fluid.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karthikeyan et al. (Journal of Cell Science 107: 3213-3222, November 1994), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). The teachings of Karthikeyan as evidenced by Kleef have been presented in the 102(b) rejection numbered 8. Karthikeyan does not teach a diagnostic kit for glypican-1 detection wherein the human cancer cell is a breast cancer cell.

However, Birembaut teaches the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to assay breast cancer cells for glypican-1 as taught by Birembaut. One of ordinary skill in the art would have been motivated to combine the teachings of all of the references with a reasonable expectation of success by teachings in the Birembaut reference because several organ types with benign and malignant cancer, including breast cancer cells were evaluated for glypican-1 with an glypican-1 antibody.

15. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivins et al. (Developmental Biology 184: 320-332, April 15, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in

view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). The teachings of Ivins as evidenced by Kleef have been presented in the 102(b) rejection numbered 8. Ivins does not teach a diagnostic kit for glypican-1 detection wherein the human cancer cell is a breast cancer cell.

However, Birembaut teaches the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to assay breast cancer cells for glypican-1 as taught by Birembaut. One of ordinary skill in the art would have been motivated to combine the teachings of all of the references with a reasonable expectation of success by teachings in the Birembaut reference because several organ types with benign and malignant cancer, including breast cancer cells were evaluated for glypican-1 with an glypican-1 antibody.

16. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liang et al. (The Journal of Cell Biology 139(4): 851-864, November 17, 1997), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). The teachings of Liang as evidenced by Kleef have been presented in the 102(b)

rejection numbered 8. Liang does not teach a diagnostic kit for glypican-1 detection wherein the human cancer cell is a breast cancer cell.

However, Birembaut teaches the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to assay breast cancer cells for glypican-1 as taught by Birembaut. One of ordinary skill in the art would have been motivated to combine the teachings of all of the references with a reasonable expectation of success by teachings in the Birembaut reference because several organ types with benign and malignant cancer, including breast cancer cells were evaluated for glypican-1 with an glypican-1 antibody.

17. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Litwack et al. (Developmental Dynamics 211: 72-87, January 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). The teachings of Litwack as evidenced by Kleef have been presented in the 102(b) rejection numbered 8. Litwack does not teach a diagnostic kit for glypican-1 detection wherein the human cancer cell is a breast cancer cell.

However, Birembaut teaches the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to assay breast cancer cells for glypican-1 as taught by Birembaut. One of ordinary skill in the art would have been motivated to combine the teachings of all of the references with a reasonable expectation of success by teachings in the Birembaut reference because several organ types with benign and malignant cancer, including breast cancer cells were evaluated for glypican-1 with an glypican-1 antibody.

18. Claims 1-6, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (The Journal of Biological Chemistry 273(35): 22825-22832, August 28, 1998), as evidenced by Kleeff et al. (J. Clin. Invest. 102(9): 1662-1673, November 1998), and in view of Birembaut et al. (Journal of Pathology 145: 283-296, April 1985). The teachings of Liu as evidenced by Kleef have been presented in the 102(b) rejection numbered 8. Liu does not teach a diagnostic kit for glypican-1 detection wherein the human cancer cell is a breast cancer cell.

However, Birembaut teaches the detection of heparin sulphate proteoglycan also art known as glypican-1 in intraductal and intralobular carcinomas of the mammary gland with antibodies, see abstract; page 284, column 1, Material section, 2nd

paragraph; page 284, column 2, Antisera section; and page 285, Mammary gland section. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention was made to assay breast cancer cells for glypican-1 as taught by Birembaut. One of ordinary skill in the art would have been motivated to combine the teachings of all of the references with a reasonable expectation of success by teachings in the Birembaut reference because several organ types with benign and malignant cancer, including breast cancer cells were evaluated for glypican-1 with an glypican-1 antibody.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER

Alana M. Harris, Ph.D.
13 October 2006